

REMARKS/ARGUMENTS

The Office Action has been carefully considered. Before entry of this paper, the status of the application is as follows:

- Claims 1-13, 15, 17-20, 24-29, 31-54, 56, 58-61, 65-70, 72-79, and 81-84 are pending in the application.
- Claim 83 has been withdrawn from consideration.
- Claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin *et al.* (U.S. Pub. No. 2004/0138712; hereinafter “Tamarkin”).
- Claims 11, 12, 15, 17, 18, 31, 32, 35, 36, 38, 52, 53, 56, 58, 59, 72, 73, 76, 77, and 79 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin and further in view of Ella *et al.* (U.S. Pub. No. 2004/0260209; hereinafter “Ella”).
- Claims 33, 34, 37, 74, 75, and 78 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin, in view of Ella and further in view of Hansjurgens *et al.* (US 5,573,552; hereinafter “Hansjurgens”).
- Claims 39, 81, and 82 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Cosman (U.S. Pat. No. 6,405,572; hereinafter “Cosman”).
- Claims 41, 42, and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Lia *et al.* (U.S. Pub. No. 2004/0019286; hereinafter “Lia”).

In this paper, claims 1, 12, 43, and 53 have been amended. Support for these amendments can be found in the as-filed claims, for example, original claims 18 and 59. Additionally, claims 18 and 59 have been cancelled.

In view of the amendments above and the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejections of all the pending claims.

Claim Rejections – 35 U.S.C. § 103(a)

In the Action, claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin. Applicant disagrees and hereby traverses.

Nevertheless, without conceding the validity of the rejection and solely for facilitating the prosecution of the present application, the independent claims (1 and 43) have been amended in

this paper. Applicant submit that the claims as amended are now inventive over EP 1,219,278 in view of Tamarkin. In one aspect, the present invention relates to a treatment system for reducing body perimeter at a region of treatment, wherein the system includes “an ultrasound apparatus, for transmitting ultrasound waves to said region of treatment, at a minimum intensity of 1.5 W/cm²; and an electrical stimulation apparatus, for applying electrical stimulation to said region of treatment simultaneously with said transmission of ultrasound waves, wherein said electrical stimulation comprises interferential stimulation” (*see* pending claim 1). In another aspect, this invention relates to a treatment method comprising steps, such as transmitting ultrasound waves at a minimum intensity of 1.5 W/cm² to the region of treatment, and applying electrical stimulation to the treatment region, wherein the electrical stimulation includes interferential stimulation (*see* pending claim 43). Applicant contends that neither of the cited references discloses such a treatment system/method as recited and claimed in the pending claims of this application.

Applicant submits that EP 1,219,278 does not disclose a treatment system (e.g., a ultrasonic massaging device), in which ultrasound waves would be transmitted at the intensity level as specified in this invention. As a matter of fact, for safety reasons, existing ultrasound treatment devices generally operate at an intensity level below 1.5 W/cm². In contrast, Applicant submits that the claimed treatment system/method would not achieve the intended technical results with an operational intensity below 1.5 W/cm², which is the minimum level required to produce cavitation to an extent necessary for inducing fat dissolution and cracks in the collagen fibers of the treatment region (*see*, e.g., page 10, lines 28-30 of the as-filed application). It is believed that the cavitation effects triggered by the ultrasound waves is crucial for a successful implementation of the treatment system/method presently recited and claimed (*see* also line 27 at page 9 through line 12 at page 10 of the as-filed application). The present inventor has discovered that cavitation begins to take effect when the ultrasound waves are transmitted at an intensity between 1.5-2.1 W/cm², and that the cavitation effect is more substantial once the intensity of the ultrasound is above this range. As such, Applicant contends the limitation of the operational intensity (as recited in the pending claims) is sufficient to differentiate the presently claimed subject matter from the systems disclosed in EP 1,219,278.

Furthermore, Applicant submits that EP 1,219,278 does not teach an apparatus which applies any form of electrical stimulation (let alone the unique type of “interferential

stimulation”) to the region of treatment, together and simultaneously with the ultrasound application. In view of the foregoing discussions, Applicant submits that EP 1,219,278 fails to disclose each and every element of the presently claimed treatment system/method. Moreover, Applicant contends that the system/method claimed in this application and those disclosed in EP 1,219,278 are patentably distinct.

Applicant further submits that Tamarkin does not teach the presently claimed subject matter either. Specifically, Tamarkin does not teach a **simultaneous application** of ultrasound and interferential stimulation to the region of treatment, **for reducing body perimeter** at the region of treatment. Arguably, the stimulating device 12 as disclosed in Tamarkin at paragraph [0053] may be an iontophoresis device, or an electrical stimulation device, or a combination of an iontophoresis device, and an electrical stimulation device, which may be construed as including interferential current stimulation (*see* Tamarkin at paragraph [0031]). Nevertheless, the iontophoresis device of Tamarkin is intended to enhance the delivery of an active substance into the skin, as opposed to the claimed invention where the ultrasound application is intended to achieve reduced body perimeter (such as, the breakdown and dissolution of cellulite) through the cavitation effects (*see*, e.g., line 4, page 9 through line 2, page 11 of the as-filed application). For apparent safety concerns, one skilled in the art would only operate the apparatus as disclosed in Tamarkin at an ultrasound intensity far below 1.5 W/cm^2 to achieve its intended purpose (that is, to enhance delivery of the active substance into the skin), as one would understand that cavitation effects are unnecessary for the delivery enhancement. As such, Applicant submits that the addition of Tamarkin also fails to teach the presently claimed system/method. Therefore, Applicant submits that the combination of EP 1,219,278 and Tamarkin does not teach or disclose the present invention, as the combination still fails in teaching each and every element of the presently claimed subject matter (for example, ultrasound waves are applied to the treatment region at an intensity above 1.5 W/cm^2 , and treatment on the treatment region with interferential electrical stimulation, etc.).

Moreover, Applicant contends that neither EP 1,219,278 nor Tamarkin provides any motivation or suggestion to a person of ordinary skill in the art to arrive at the presently claimed subject matter. Indeed, when one skilled in the art is presented with the problem which the present inventor was facing (that is, to reduce body perimeter at a region treated with ultrasound), one would not consider and rely on Tamarkin for solutions, as Tamarkin is intended

for achieving a fundamentally different purpose - enhancing delivery of an active substance into the skin. Likewise, Applicant submits that, when one skilled in the art is presented with the technical problem which the present inventor had been facing, one would not consider EP 1,219,278 for solving the problem, as EP 1,219,278 merely teaches ultrasound massaging and does not disclose any electrical stimulation of the body for reducing body perimeter through interferential electrical stimulation of the treatment region. Accordingly, Applicant contends that one skilled in the art would not be motivated to make a combination of EP 1,219,278 and Tamarkin for arriving at the present invention. Even *assuming* that one is to make such a combination, one would still fail in the attempt as the combination of EP 1,219,278 and Tamarkin does not teach each and every element of the present invention (as above discussed).

Therefore, Applicant submit that claims 1-10, 13, 19-20, 24-29, 40, 43-51, 54, 60-61, and 65-70 are patentable over EP 1,219,278, either alone or in combination with Tamarkin. Thus, the reconsideration and withdrawal of the rejection over EP 1,219,278 in view of Tamarkin is proper and the same is requested.

In this Action, claims 11, 12, 15, 17, 18, 31, 32, 35, 36, 38, 52, 53, 56, 58, 59, 72, 73, 76, 77, and 79 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin and further in view of Ella. Applicant disagrees and hereby traverses.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin is applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin.

Applicant contends that the addition of Ella still fails in rendering the presently claimed subject matter obvious. The Action asserts that Ella discloses an ultrasound apparatus which operates at an intensity of 1 to 3 W/cm² (*see* page 5 of the Action). Applicant disagrees. Although it is noted that Ella discloses an ultrasound apparatus operating at the intensity of 0.5 W/cm² when using a continuous waveform, and an intensity of 120 mW/cm² when using a pulsed waveform, Ella nevertheless states that:

“a safe standard for a continuous waveform ultrasound is about 1 W/cm², for about 15 minutes, for general muscle treatment. For facial treatment, it is about 0.5 W/cm², for about 10 minutes. A safe standard for a pulse waveform is about 240 mW/cm². By

comparison, shattering kidney stones requires about 10 W/cm².” (see, e.g., Ella at paragraphs [0018] & [0020])

Thus, according to the safety standard as delineated in Ella, one skilled in the art would conclude that the ultrasound apparatus disclosed in Ella for massaging and reducing body fat and cellulite, shall be operated at a maximum intensity of 1 W/cm². As such, Applicant contends that Ella does not teach a treatment system (or method) in which an ultrasound apparatus operates at a minimum intensity of 1.5 W/cm² (as presently claimed). Accordingly, Applicant submits that the addition of Ella still fails in curing the deficiencies of EP 1,219,278 and Tamarkin, at least due to the fact that Ella does not teach (if not teaches away from) an ultrasound apparatus operating at a minimum intensity of 1.5 W/cm².

Applicant further contends that Ella does not offer the much-needed motivation or suggestion for a skilled artisan to reach the presently claimed system/method. As above discussed, Ella states clearly that the safety concerns mandate its ultrasound apparatus to be operated at the maximum intensity of 1.0 W/cm², which is far below the level as required for the presently claimed apparatus/method. Such an intensity level at which the Ella’s apparatus is operated falls short to induce sufficient cavitation effects as required for inducing fat dissolution and cracks in the collagen fibers of the treatment region (which is one of the intended purposes for the presently claimed system/method). Indeed, one skilled in the art would not be motivated to come up with the claimed invention in view of the explicit teachings in Ella.

As such, Applicant submits that claims 11, 12, 15, 17, 18, 31, 32, 35, 36, 38, 52, 53, 56, 58, 59, 72, 73, 76, 77, and 79 are patentable over EP 1,219,278 in view of Tamarkin and further in view of Ella. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

In addition, claims 33, 34, 37, 74, 75, and 78 stand rejected in the Action under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin and Ella, and further in view of Hansjurgens. The rejection is hereby traversed.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin and Ella is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin and Ella.

Applicant contends that the addition of Hansjurgens still fails in rendering the presently claimed subject matter obvious. Applicant notes that Hansjurgens does not teach or suggest a treatment system/method for reducing body perimeter at a region of treatment, wherein an ultrasound device is operated at a minimum intensity of 1.5 W/cm^2 . Indeed, Hansjurgens does not teach or disclose an ultrasound apparatus at all. Accordingly, Applicant submits that the addition of Hansjurgens still fails in curing the deficiencies of EP 1,219,278, Tamarkin and Ella, at least due to the fact that Hansjurgens does not teach or disclose using an ultrasound apparatus with an operational intensity at a minimum level of 1.5 W/cm^2 . Moreover, Applicant notes that Hansjurgens does not provide any motivation or suggestion for a skilled artisan to arrive at the presently claimed system/method.

Accordingly, Applicant submits that claims 33, 34, 37, 74, 75, and 78 are patentable over EP 1,219,278, in view of Tamarkin and Ella, and further in view of Hansjurgens. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

In addition, claims 39, 81, and 82 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Cosman. The rejection is hereby traversed.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin.

Applicant contends that the addition of Cosman still fails in rendering the presently claimed subject matter obvious. Specifically, Cosman does not teach or suggest using an ultrasound device for reducing body perimeter at the region of treatment, let alone using the ultrasound device with an operational intensity of 1.5 W/cm^2 or higher for that purpose. Instead of using an ultrasound apparatus for reducing body perimeter, Applicant notes that Cosman only teaches or discloses ultrasound imaging. Accordingly, Applicant submits that the addition of Cosman still fails in curing the deficiencies of EP 1,219,278 and Tamarkin.

Accordingly, Applicant submits that claims 39, 81, and 82 are patentable over EP 1,219,278, in view of Tamarkin, and further in view of Cosman. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

Still further, claims 41, 42, and 84 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 1,219,278 in view of Tamarkin, and further in view of Lia. This rejection is now traversed.

Applicant respectfully submits that the above-reasoning rebutting the rejection over EP 1,219,278 in view of Tamarkin is also applicable in this section of discussion, as the claimed treatment system/method is patentable over EP 1,219,278 in view of Tamarkin.

Applicant contends that the addition of Lia still fails in rendering the presently claimed subject matter obvious. In particular, Lia does not teach using an ultrasound apparatus for reducing body perimeter, let alone operating the apparatus at an intensity of 1.5 W/cm^2 or higher. As such, Applicant submits that the combination of EP 1,219,278, Tamarkin and Lia would not render the claimed subject matter obvious, as none of them teaches or suggests a system/method which employs an ultrasound apparatus to transmit ultrasound waves at a minimum intensity of 1.5 W/cm^2 , and an electrical stimulation apparatus to apply interferential electrical stimulation to the treatment region together with the ultrasound application.

Accordingly, Applicant submits that claims 41, 42, and 84 are patentable over EP 1,219,278, in view of Tamarkin, and further in view of Lia. Thus, reconsideration and withdrawal of the instant rejection is proper and the same is requested.

CONCLUSIONS

In view of the foregoing, Applicant submits that all the pending claims of this application are allowable. Applicant respectfully requests entry of this Amendment and Response, reconsideration, and early favorable action by the Examiner. The Examiner is cordially invited to contact Applicant's undersigned representative at the number listed below to discuss any outstanding issues. Applicants thank the Examiner in advance for this courtesy.

It is believed that no fee is required for this submission. However, if any fee is deemed necessary, the Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 04-1105, under the Order No. 64030(303625)

Respectfully submitted,

Date: January 4, 2010
Reg. No. 61,637

Tel. No.: (617) 239-0416
Fax No.: (888) 325-9725

Email: wyang@eapdlaw.com

Electronic signature: /Weiying Yang/
Weiying Yang
Attorney for Applicant
Edwards Angell Palmer & Dodge LLP
Huntington Avenue
P.O. Box 55874
Boston, Massachusetts 02205-5874
www.eapdlaw.com